



USSN: 10/772,020

Applicant: SCHRIER *et al.*

Attorney Docket: I-2000.537 US D2

Centre for Applied Microbiology and Research
&
European Collection of Cell Cultures

This document certifies that Virus
(Deposit Ref. V00012608) has been accepted as a patent deposit,
in accordance with
The Budapest Treaty of 1977,
with the European Collection of Cell Cultures on 26th January 2000

P.J.Packer

Dr P J Packer,
Quality Manager, ECACC

CAMR
Today's Research
Tomorrow's Health



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APPENDIX 3

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BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSES OF PATENT PROCEDURE

TO

INTERNATIONAL FORM

AKZO NOBEL NV
VELPERWEG 76
6824 BM ARNHEM
THE NETHERLANDS

NAME AND ADDRESS
OF DEPOSITOR

I. IDENTIFICATION OF THE MICROORGANISM	
Identification reference given by the DEPOSITOR:	Accession number given by the INTERNATIONAL DEPOSITORY AUTHORITY:
CAV (CAA 319)	V00012608
II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION	
The microorganism identified under I above was accompanied by:	
<input checked="" type="checkbox"/> A scientific description	
<input type="checkbox"/> A proposed taxonomic designation	
(Mark with a cross where applicable)	
III. RECEIPT AND ACCEPTANCE	
This International Depository Authority accepts the microorganism identified under I above, which was received by it on 26 th January 2000 (date of the original deposit) ¹	
IV. RECEIPT OF REQUEST FOR CONVERSION	
The microorganism identified under I above was received by this International Depository Authority on (date of the original deposit) and A request to convert the original deposit to a deposit under the Budapest Treaty was received by it on (date of receipt of request for conversion)	
IV. INTERNATIONAL DEPOSITORY AUTHORITY	
Name: Dr P J Packer	Signature(s) of person(s) having the power to represent the International Depository Authority or of authorized officials(s):
Address: ECACC CAMR Porton Down Salisbury SP4 0JG	Date: 15/1/00

¹ Where Rule 6.4(d) applies, such date is the date on which the status of international depositary authority was acquired

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BUDAPEST TREATY ON THE INTERNATIONAL
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INTERNATIONAL FORM

TO

AKZO NOBEL NV
VELPERWEG 76
6824 BM ARNHEM
THE NETHERLANDS

VIABILITY STATEMENT

Issued pursuant to Rule 10.2 by the
INTERNATIONAL DEPOSITORY AUTHORITY
identified on the following page

NAME AND ADDRESS OF THE PARTY
TO WHOM THE VIABILITY OF STATEMENT
IS ISSUED

I. DEPOSITOR	II. IDENTIFICATION OF THE MICROORGANISM
Name: AKZO NOBEL NV Address: VELPERWEG 76 6824 BM ARNHEM THE NETHERLANDS	Accession number given by the INTERNATIONAL DEPOSITORY AUTHORITY: V00012608 Date of the deposit or of the transfer: 26 th January 2000
III. VIABILITY STATEMENT	
<p>The viability of the microorganism identified under II above was tested ¹ on ². On that date, the said microorganism was</p> <p><input checked="" type="checkbox"/> ³ viable</p> <p><input type="checkbox"/> ³ no longer viable</p>	

- 1 Indicate the date of the original deposit or, where a new deposit or a transfer has been made, the most relevant date (date of the new deposit or date of the transfer).
- 2 In the cases referred to in Rule 10.2 (a) (ii) and (iii), refer to the most recent viability test.
- 3 Mark with a cross the applicable box.

Appendix 3

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IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED

CAV (CAA 319) - ACCESSION NUMBER: V00012608

INOCULATION OF MDCC - MSB1 CELLS WITH THE VIRUS AND SERIALLY DILUTED. THE CELLS WERE OBSERVED FOR 2 WEEKS FOR CPE.

V. INTERNATIONAL DEPOSITORY AUTHORITY

Name: Dr P J Packer
ECACC CAMR
Address: Porton Down
Salisbury
Wiltshire
SP4 0JG

Signature(s) of person(s) having the power
to represent the International Depository
Authority or of authorized official(s):

Date: 30/01/00 P.J.P

4 Fill in if the information has been requested and if the results of the test were negative.

Certificate of Analysis

Product Description CAV (CAA 319)
Accession Number V00012608

Test Description: Determination of TCID₅₀ of Chicken Anaemia Virus CAA-319 as supplied by AKZO Nobel

Acceptance Criterion/Specification: MDCC-MSB1 cells were either inoculated with the test sample or left uninoculated to act as negative controls. The cells are examined microscopically for the presence absence of cytopathic effects (CPE). All negative controls must show no CPE. The viral Titre in the test sample is calculated as per Reed and Muench by analysis of CPE in test cells inoculated with a serial dilution of virus supernatant.

Date: 06/04/00

Result:

Negative Control:	Negative
CPE seen after :	4 passages
TCID ⁵⁰	$10^{-6} \times 10^{-6.37} = 10^{6.37}$
Test Sample:	Viable
Overall Result:	PASS

Test Description: The Detection of Mycoplasma by Isolation on Mycoplasma Pig Serum Agar and in Mycoplasma Horse Serum Broth.
SOP QC/MYCO/01/02

Acceptance Criterion/Specification: All positive controls (*M. pneumoniae* & *M. orale*) must show evidence of mycoplasma by typical colony formation on agar plates. Broths are subcultured onto Mycoplasma Pig Serum Agar where evidence of mycoplasma by typical colony formation is evaluated. All negative control agar plates must show no evidence of microbial growth.

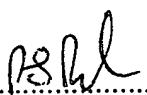
The criteria for a positive test result is evidence of mycoplasma by typical colony formation on agar. A negative result will show no such evidence.

Test Number: 20830

Date: 08/05/00

Result:

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

Authorised by.....  ECACC, Head of Quality...11/15/00... Date

Certificate of Analysis

Product Description CAV (CAA 319)
Accession Number V00012608

Test Description: Detection of Mycoplasma using a Vero indicator cell line and Hoechst 33258 fluorescent detection system.
SOP QC/MYCO/07/05

Acceptance Criterion/Specification: The Vero cells in the negative control are clearly seen as fluorescing nuclei with no cytoplasmic fluorescence. Positive control (*M. orale*) must show evidence of mycoplasma as fluorescing nuclei plus extra nuclear fluorescence of mycoplasma DNA. Positive test results appear as extra nuclear fluorescence of mycoplasma DNA. Negative results show no cytoplasmic fluorescence.

Test Number: 20830

Date: 08/05/00

Result:

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

Test Description: Detection of bacteria and fungi by isolation on Tryptone Soya Broth (TSB) and in Fluid Thioglycollate Medium (FTGM). SOP QC/BF/01/02

Acceptance Criterion/Specification: All positive controls (*Bacillus subtilis*, *Clostridium sporogenes* and *Candida albicans*) show evidence of microbial growth (turbidity) and the negative controls show no evidence of microbial growth (clear).
The criteria for a positive test is turbidity in any of the test broths. All broths should be clear for negative test result.

Test Number: 20830

Date: 08/05/00

Result:

Positive Control:	Positive
Negative Control:	Negative
Test Result:	Negative
Overall Result:	PASS

*** End of Certificate ***

Authorised by..... ECACC, Head of Quality... 11/5/00 ... Date



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Diane Payne
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Applicant: Schrier et al.
Serial No: 10/772,020
Customer No.: 31846
Attorney Docket: I-2000.537 US D2

Receipt acknowledged of the following documents in the above-identified application:

Response to Office Action of November 8, 2005 (9 pages)
ECACC accession no: 00020304 (6 pages)
ECACC accession no: V00012608 (6 pages)
Self-addressed stamped post card (1)